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EXAMINER	
SCHLIENTZ, NATHAN W	
ART UNIT	**PAPER NUMBER**
1616	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/02/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/525,591	VERMEER, CEES	
	Examiner	Art Unit	
	Nathan W. Schlientz	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 February 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *25 February 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 5/25/05
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-15 are pending. No claim is allowed at this time.

Information Disclosure Statement

The information disclosure statement filed 25 February 2005 has a Foreign Patent Document and a non-Patent Literature Document listed that are not in the English language. Therefore, the foreign patent document number DE 19955607 and the non-patent document by M. Eder have not been considered, and accordingly have been crossed out on the IDS.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 15 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-9 of copending Application No. 11/144,853. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to a method of treating a cardiovascular disease, not associated with arteriosclerosis, through administering vitamin K and optionally vitamin D. The target of the instantly claimed invention is age-related arterial stiffening, which is included in reducing or reversing calcification of a blood vessel. Accordingly, the scope of the copending claims overlap and thus they are obvious variants of one another.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112 First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claim 15 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for administering vitamin K_1, vitamin K_2, vitamin K_3, or vitamin MK4-13, and optionally vitamin D_1, vitamin D_2, vitamin D_3, alfacalcidol, dihydrotachysterol or calcitriol, does not reasonably provide enablement for

administering other derivatives thereof. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Attention is directed to In re Wands, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing Ex parte Forman, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

1) the nature of the invention
2) the state of the prior art
3) the relative skill of those in the art
4) the predictability of the art
5) the breadth of the claims
6) the amount of direction or guidance provided
7) the presence or absence of working examples
8) the quantity of experimentation necessary

The instant specification fails to provide guidance that would allow the skilled artisan to practice the instant invention without resorting to undue experimentation, as discussed in the subsections set forth herein below.

The nature of the invention.

The claimed invention relates to a method of preventing or treating age-related stiffening through administering vitamin K or a derivative thereof and optionally vitamin D or a derivative thereof.

The state of the prior art

Vitamin K is a generic name for a number of related compounds, which have in common a methylated naphthoquinone ring structure, and which vary in the aliphatic side chain attached at the 3-position. It is generally accepted that the naphthoquinone

is the functional group. However, as mentioned in the specification (page 5, lines 12-14), the aliphatic side chain differences may result in substantial changes in intestinal absorption, transport, tissue distribution, and bioavailability. Similarly, vitamin D is a generic name for a number of related compounds, which have in common a 9,10-seco-steroidal ring structure with different side chain structures, where the 9,10 carbon-carbon bond of ring B in steroids is broken. However, the differing side chain structures may result in varying effects *in vivo*.

The breadth of the claims

The recitation of derivative thereof in claim 15 indicates a plethora of structures. The bioavailability and efficacy of all such structures is not known.

The presence or absence of working examples

The specification provides detailed evaluation of vitamin K_1 and vitamin D_3, and their ability to reduce arterial stiffening. However, there is no indication of the efficacy or bioavailability of all derivatives of vitamin K or vitamin D.

The quantity of experimentation necessary

To determine how to prepare all derivatives of vitamin K and vitamin D, as well as determine their efficacy towards preventing or treating age-related arterial stiffening would require undue experimentation for one skilled in the art.

2. Claims 1-15 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating age-related stiffening of arteries, does not reasonably provide enablement for preventing age-related stiffening of arteries. The

specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Attention is again directed to In re Wands, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation.

The instant specification fails to provide guidance that would allow the skilled artisan to practice the instant invention without resorting to undue experimentation, as discussed in the subsections set forth herein below.

The nature of the invention

The claimed invention relates to a method for **preventing** or treating age-related arterial stiffening comprising administering vitamin K and optionally vitamin D.

The state and predictability of the art

There are numerous known risk factors that lead to age-related stiffening of the arteries. Vitamin supplements are known to have many health benefits, but they are not a substitute for a healthy diet. (The Merck Manual of Medical Information - Second Home Edition, February 2003). Also, many steps can be taken that reduce the risk or coronary artery diseases; however, there is no proof that any one treatment or lifestyle change will **prevent** coronary artery diseases.

The breadth of the claims

The claims are broad in that they are drawn to the treatment or **prevention** of age-related stiffening of the arteries. Prevention indicates a 100% success rate, which

implies the patients that are administered the presently claimed invention will not experience any degree of age-related stiffening of the arteries.

The amount of direction or guidance provided and

The presence or absence of working examples

The specification does not provide any direction or guidance with respect to **preventing** age-related stiffening of the arteries. Also, the specification does not provide any examples that would indicate the instantly claimed invention could **prevent** age-related stiffening of the arteries. The specification provides an example where postmenopausal women were treated with one of three compositions: (1) a placebo, (2) a composition comprising vitamin D3, (3) or a composition comprising vitamin D_3 and vitamin K_1 (page 8, lines 29-35). The example shows the ability of the instantly claimed invention to treat age-related stiffening of the arteries; however, there is no indication this treatment will afford **prevention**.

The quantity of experimentation necessary

Undue experimentation would be required for a person skilled in the pertinent art to determine the ability of the presently claimed invention to **prevent** age-related stiffening of the arteries. The person would have to determine the ability of the instantly claimed invention to maintain peak elasticy in the arteries for subjects experiencing multiple risk factors. Therefore, the person skilled in the art would have to undertake undue experimentation to practice the instantly claimed invention.

Genetech, 108 F.3d at 1366 states that "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "patent

protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable".

Claim Rejections - 35 USC § 112 Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 1-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is drawn to the use of a composition in the manufacture of a medicament or nutritional for treating or preventing **age-related** stiffening of arteries. However, it is unclear what population is encompassed by the term "age-related". The specification states, "Peak elasticities are achieved at about age 14-15, after which [arteries] deteriorate gradually." (page 1, lines 25-26). The specification also states, "Arteries, especially the larger elastic arteries such as the common carotid artery, become stiffer with age." (page 1, lines 24-25). It is unclear whether any person over the age 15 is encompassed in the **age-related** category since that is after the peak elasticity and gradual deterioration has begun. Therefore, the metes and bounds of the claim are unclear.

2. Claims 1-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-14 provides for the use of a composition comprising vitamin K in the manufacture of a medicament, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

1. Claims 1-14 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

For the purposes of examination, Claim 1 is being construed by the examiner to be a method for the manufacture of a medicament or nutritional formulation comprising vitamin K or a derivative thereof, optionally together with vitamin D or a derivative thereof, for treating or preventing age-related stiffening of arteries, not associated with arteriosclerosis. Accordingly, Claims 2-14 are construed as methods for the manufacture of a medicament or nutritional formulation comprising further limitations, and are dependent from Claim 1.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. Claims 1, 4-10 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by UK Patent Application GB 2 180 747 A (hereinafter Kreitzman).

Claims 1-11 are construed by the examiner to be drawn to a method for the manufacture of a medicament or nutritional formulation comprising vitamin K or a derivative thereof, optionally together with vitamin D or a derivative thereof. Preferably the vitamin K is in the range 50-1000 μg and the vitamin D is vitamin D_3 (cholecalciferol) in the range 5-10 μg. The medicament or nutritional further comprises one or more components selected from the group listed in claim 10, which includes Calcium, Magnesium, Potassium, Zinc, folic acid, vitamin C, and vitamin E. Also, the nutritional is a food or beverage product or a dietary; supplement.

Kreitzman discloses a composition which is formulated comprising 10 μg vitamin D_3, 140 μg vitamin K, Calcium, Magnesium, Potassium, Zinc, folic acid, vitamin C, and

vitamin E (Example 4, page 6). Kreitzman further discloses the composition as a pharmaceutical dietary pharmaceutical (abstract).

It is noted that the recitations of the intended use "for treating or preventing age-related stiffening of arteries, not associated with arteriosclerosis", "for administration to a postmenopausal woman", and "administered over a period of at least 12 months, preferably at least 36 months" have not been given patentable weight to distinguish over Kreitzman because the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Since Kreitzman discloses compositions that are the same as those claimed, they would be capable of performing the intended use, as claimed. Therefore, Kreitzman anticipates all the limitations of the instant claims.

2. Claims 1-3 and 5-10 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,914,073 (hereinafter Boulos et al.).

The instant claims are construed by the examiner to be drawn to a method for the manufacture of a medicament or nutritional formulation comprising vitamin K or a derivative thereof, optionally together with vitamin D or a derivative thereof. Preferably the vitamin K is vitamin K_1 (a.k.a. phylloquinone or phytonadione) and the vitamin D is vitamin D_3 (cholecalciferol). The medicament or nutritional further comprises one or

more component selected from the group listed in claim 10, which includes folic acid, and vitamin E.

Boulos et al. disclose a formulation comprising vitamin D_3, vitamin K_1, vitamin E, and folic acid (column 14, Formulation II). Boulos et al. further disclose the vitamins are designed specifically for optional cardioprotective effect (column 16, lines 32-34). Boulos et al. further disclose a method of providing a cardiovascular benefit to a human comprising orally administering a daily dose of a composition comprising vitamin E and other vitamins, such as vitamin K and vitamin D (claims 11 and 12).

It is noted that the recitations of the intended use "for treating or preventing age-related stiffening of arteries, not associated with arteriosclerosis", "for administration to a postmenopausal woman", and "administered over a period of at least 12 months, preferably at least 36 months" have not been given patentable weight to distinguish over Boulos et al. because the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Since Boulos et al. discloses compositions that are the same as those claimed, they would be capable of performing the intended use, as claimed. Therefore, Boulos et al. anticipate all the limitations of the instant claims.

3. Claim 15 is rejected under 35 U.S.C. 102(e) as being anticipated by Boulos et al.

The instant claim is drawn to a method of treating or preventing age-related arterial stiffening, not associated with arteriosclerosis, comprising administering vitamin K and vitamin D.

Boulos et al. disclose a method of providing a cardiovascular benefit to a human comprising orally administering a daily dose of a composition comprising vitamin E and other vitamins (claim 12). Boulos et al. further disclose the vitamins as comprising vitamin K and vitamin D (claim 11, and column 14: Vitamin Premix). Therefore, Boulos et al. fully anticipate all the limitations of the instant claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in Graham v. John Deere Co., 383 U.S. 1,148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. Claims 1-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kreitzman.

Applicant claims:

The Applicant's claims are being construed as a method for the manufacture of a medicament or nutritional preferably comprising 0.5-1.5 mg vitamin K_1, 5-10 μg vitamin D_3, 450-550 mg Calcium, 7-12 mg Zinc, and 100-200 mg Magnesium.

Determination of the scope and content of the prior art

(MPEP 2141.01)

The teachings of Kreitzman are described above. Essentially, Kreitzman teaches a composition given in three daily dosages wherein the total amount given comprises 140 μg vitamin K_1, 10 μg vitamin D_3, 800 mg Calcium, 15 mg Zinc, and 400 mg Magnesium (page 6, example 4).

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

Kreitzman does not teach the vitamin K, vitamin D, Calcium, Zinc, and Magnesium in the exact ranges claimed in the instant claims. However, the examiner respectfully points out the following from MPEP 2144.05: "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." I*n re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955); see also Peterson, 315 F.3d at 1330, 65 USPQ2d at 1382 ("The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of

percentage ranges is the optimum combination of percentages."); *In re Hoeschele*, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969); Merck & Co. Inc. v. Biocraft Laboratories Inc., 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989); *In re Kulling*, 897 F.2d 1147, 14 USPQ2d 1056 (Fed.Cir. 1990); and *In re Geisler*, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997).

Finding of *prima facie* obviousness

Rational and Motivation (MPEP 2142-43)

Therefore, it would have been *prima facie* obvious for one skilled in the art at the time of the invention to prepare a medicament or nutritional formulation comprising vitamin K_1, vitamin D_3, Calcium, Zinc, and Magnesium within the ranges of the instant claims, because Kreitzman teaches a composition with those components and it would be routine experimentation to optimize the ranges.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

2. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,968,917 (hereinafter Clayton).

Applicant claims:

The instant claim is drawn to a method for treating or preventing age-related stiffening of the arteries, not associated with arteriosclerosis, comprising administering vitamin K and optionally vitamin D.

Determination of the scope and content of the prior art

(MPEP 2141.01)

Clayton teaches a method for preventing or treating osteoporosis through administering a therapeutically effective amount of diosgenin, vitamin K and vitamin D (claim 3). Clayton further teaches a clinical trial where post-menopausal female volunteers received a composition comprising 120 μg vitamin K_1 and 20 μg vitamin D_3 (column 2, lines 38-47).

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

Clayton does not teach the composition comprising vitamin K and vitamin D to treat age-related stiffening of the arteries. However, the specification teaches administering the composition of the instantly claimed invention to a group of healthy postmenopausal women, and analyzing the effects on arterial stiffening (). Since the target subject is the same, postmenopausal women, and the compositions are the same, the invention of Clayton would inherently possess the property of treating age-related arterial stiffening. The examiner respectfully points out the following from MPEP

2112: "The discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). In *In re Crish*, 393 F.3d 1253, 1258, 73 USPQ2d 1364, 1368 (Fed. Cir. 2004), the court stated that "just as the discovery of properties of a known material does not make it novel, the identification and characterization of a prior art material also does not make it novel."

Finding of *prima facie* obviousness

Rational and Motivation (MPEP 2142-43)

Therefore, it would have been *prima facie* obvious for one skilled in the art at the time of the invention to treat age–related stiffening of the arteries, not associated with arteriosclerosis, through administering vitamin K and optionally vitamin D.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nathan W. Schlientz whose telephone number is 571-272-9924. The examiner can normally be reached on 8:30 AM to 5:00 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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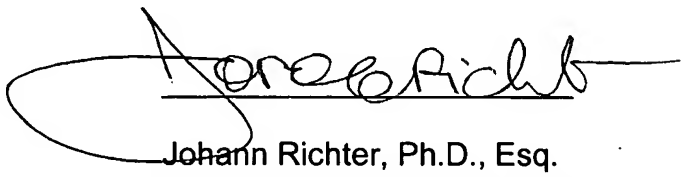

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